

**Notice of Allowability**

Application No.

10/807,961

Examiner

Eric S. Olson

Applicant(s)

GROSS, RICHARD A.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment submitted February 7, 2007.
2. ☒ The allowed claim(s) is/are 1-3, 8, 9, and 22, renumbered 1-6.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date March 29, 2007.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

 4/10/07  
SHAOJIA ANNA JIANG, PH.D.  
SUPERVISORY PATENT EXAMINER

### Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was provided by Lawrence P. Colton in a telephone interview March 29, 2007.

Claim 8 is amended to read:

8. The method as claimed in claim 1, wherein the ~~sophorolipid~~ mixture is comprises a 17-L-[(2'-O- $\beta$ -D-glucopyranosyl- $\beta$ -D-glucopyranosyl)-oxy]-cis-9-octadecanoate based sophorolipid.

In addition, claims 4-7, 10-14, 16-21, and 23-35 are cancelled.

The title is amended as follows:

~~Treatment and Prophylaxis~~ of Sepsis and Septic Shock

The abstract is amended as follows:

A method and composition for the ~~prophylaxis or treatment~~ of humans or animals for septic shock and sepsis using a mixture of sophorolipids.

### **Detailed Action**

This office action is a response to applicant's amendment submitted February 7, 2007 wherein claims 1, 4-21, 23-27, 34, and 35 are amended and claims 25 is cancelled. This application claims priority to provisional application 60/457070, filed March 24, 2004.

Claims 1-14 and 16-35 are pending in this application and examined on the merits herein.

Applicant's amendment, submitted February 7, 2007, with respect to the rejection of instant claims 33 and 34 under 35 USC 112, second paragraph, for omitting essential steps, has been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 7, 2007, with respect to the rejection of instant claims 8-17 under 35 USC 112, second paragraph, for lacking antecedent basis in the base claim, has been fully considered and found to be persuasive to remove the rejection as claims 10-17 are no longer pending and claims 8-9 are now drawn to a mixture rather than to a single sphorolipid. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 7, 2007, with respect to the rejection of instant claims 1-26, 33, and 34 under 35 USC 112, first paragraph, for lacking

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enablement for a method of prophylaxis, has been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer drawn to a method of prophylaxis. Therefore the rejection is withdrawn.

Applicant's amendment, submitted February 7, 2007, with respect to the rejection of instant claim 34 under 35 USC 102(b), for being anticipated by Davila et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claim is no longer pending. Therefore the rejection is withdrawn.

### **Reasons for Allowance**

Currently, claims 1-3, 8, 9, and 22 are pending in this application and have been examined on the merits herein. The claimed therapeutic methods described in the instant claims are not seen to be taught or fairly suggested by the prior art.

Reasons for allowance are as follows: The claimed methods of treating sepsis and septic shock recited by the aforementioned claims are seen to be novel and non-obvious over the prior art and are directed to subject matter adequately described and enabled by Applicant's specification. Written description of the claimed methods is found, for example, in examples 1 and 2 on pp. 9-15 of the instant specification. These examples are sufficient to enable one skilled in the art to use the claimed invention. One skilled in the art would be enabled to make the sophorolipids used in the claimed invention by the fermentation and isolation protocols (p. 4, line 18 – p. 6, line 27) found

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in the instant specification. In addition, the fermentation and purification of sophorolipids is well known in the prior art.

The prior art does not teach any method of treating sepsis or septic shock using any mixture containing sophorolipids. The earliest mention in the literature of any use of sophorolipids to treat sepsis or septic shock is in Kandil et al. (Reference included with PTO-892) This reference was published in September 2003, after the effective filing date of the instant application. Also, the Applicant, Richard Gross, is listed as an author in this publication. For these reasons, the subject matter is allowable over the prior art.

Accordingly, Applicant's amendment submitted February 7, 2007, along with the enclosed examiner's amendment, is sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3/29/07

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